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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,946	08/08/2001	Mark J. Evans	0630/1G703US2	3104
7278	7590	01/30/2004	EXAMINER	
DARBY & DARBY P.C.			PAK, YONG D	
P. O. BOX 5257			ART UNIT	
NEW YORK, NY 10150-5257			PAPER NUMBER	
			1652	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,946

Applicant(s)

EVANS ET AL.

Examiner

Yong D Pak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 16 and 21-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10, 13-15, 17-20 and 47-55 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed on November 18, 2003, amending claims 8, 10-14, 17 and 18 and adding claims 47-55, has been entered.

Claims 1-55 are pending.

Election/Restrictions

Claims 1-7, 16 and 21-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Objections

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 18 is drawn to a polynucleotide comprising 20 consecutive nucleotide bases of SEQ ID NO:1. However, claim 19 is drawn to a polynucleotide comprising 10 consecutive nucleotide bases of SEQ ID NO:1. Therefore, the scope of the polynucleotide of claim 19 is much more broad than the scope of claim 18.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 18-20 are drawn to DNA that is at least 20 bases in length that hybridizes to SEQ ID NO:1 and that does not hybridize to DNA encoding to other lysyl oxidase. A description of only 20 nucleotide bases, which represents about 1% of the whole structure of SEQ ID NO:1, amount to insufficient description of the structure of the DNA molecule in this claim. The specification does not contain any disclosure of the structure and function of all EER-7 DNA fragments or portions thereof. The genus of DNA that comprise these above fragments and portions of EER-7 DNA is a large variable genus with the potentiality of encoding many different proteins or a large variable genus of polynucleotides with an unknown function. Therefore, many structurally and functionally unrelated DNA are encompassed within the scope of these claims, including partial DNA sequences. The specification fails to describe any other representative species by any identifying characteristics or properties or function other than its hybridization with SEQ ID NO:1 and fails to provide any structure: function correlation present in all members of the claimed genus. Given this lack of the description of the representative species encompassed by the genus of the claim, the

specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 18-20.

Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding the EER-7 of SEQ ID NO:2, does not reasonably provide enablement for DNA molecules of unlimited structure and function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims encompass molecules having very low structural similarity to SEQ ID NO:1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of constructs broadly encompassed by the claims. The claims are drawn to polynucleotides comprising at

least 20 nucleotide bases that hybridize to any portion of SEQ ID NO:1 other than the lysyl oxidase region. A polynucleotide of 20 nucleotide bases will hybridize to a wide range of polynucleotide and the specification does not teach how to use these varying polynucleotides/oligonucleotides. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other EER-7 is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of polynucleotides where the expectation of obtaining similar sequences is unpredictable. It is unpredictable if a polynucleotide that hybridizes to SEQ ID NO:1 will not also hybridize to other lysyl oxidases under the defined stringent condition.

Therefore, one of ordinary skill would require guidance in order to make DNA encoding a EER-7 protein different from SEQ ID NO:2 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by

Bonaldo et al.

Bonaldo et al. (form PTO-892) teach a polynucleotide that is at least 20 consecutive bases in length that hybridizes to SEQ ID NO:1 under stringent conditions. Therefore, the teaching of Bonaldo et al. anticipates claims 18-20.

Claims 8-10, 13-15, 17-20 and 47-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Meyers.

Meyers (U.S. Patent Application Publication No. US 2003/0059919 – form PTO-1449) teach a DNA molecule encoding a lysyl oxidase that is 99.9% identical to SEQ ID NO:2, differing by only one residue at position 405 (pages 413-415). The lysyl oxidase of Meyers comprises of four scavenger receptor cysteine-rich (SRCR) domains that is greater than 80% similar to SQ ID NO:3, 4, 5 and 6 and the oxidase of Meyers also comprises of the conserved catalytic domain of lysyl oxidase enzymes as depicted in SEQ ID NO:7. Meyers also teaches vectors comprising said DNA, host cell transfected with said vector, a method of producing the protein and nucleic acid molecules of at least 20 bases that hybridizes under stringent conditions with SEQ ID NO:1, which are

also labeled (see claims, pages 432-433). Therefore, the teachings of Meyers anticipate claims 8-10, 13-15, 17-20 and 47-55.

Claims 8-10, 13-15, 17-20 and 47-55 are rejected under 35 U.S.C. 102(g) as being anticipated by Meyers.

Meyers (U.S. Patent Application Publication No. US 2003/0059919 – form PTO-1449) teach a DNA molecule encoding a lysyl oxidase that is 99.9% identical to SEQ ID NO:2, differing by only one residue at position 405 (pages 413-415). The lysyl oxidase of Meyers comprises of four scavenger receptor cysteine-rich (SRCR) domains that is greater than 80% similar to SQ ID NO:3, 4, 5 and 6 and the oxidase of Meyers also comprises of the conserved catalytic domain of lysyl oxidase enzymes as depicted in SEQ ID NO:7. Meyers also teaches vectors comprising said DNA, host cell transfected with said vector, a method of producing the protein and nucleic acid molecules of at least 20 bases that hybridizes under stringent conditions with SEQ ID NO:1, which are also labeled (see claims, pages 432-433). Therefore, the teachings of Meyers anticipate claims 8-10, 13-15, 17-20 and 47-55.

Response to Amendment

The affidavit filed on November 18, 2003 under 37 CFR 1.131 is sufficient to overcome the Meyers et al. (US Patent Application No. 2002/0068322) reference because the application has been abandoned.

Allowable Subject Matter

Claims 11-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner



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